DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

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JUN - 8 2001

WARNING LETTER
ONPLDS 14-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Julia Sabin
President
Smucker Quality Beverages, Inc.
P.O. Box 369
Speedway Avenue
Chico, California 95927

Dear Ms. Sabin:

The Food and Drug Administration (FDA) has reviewed the label of your R.W. Knudsen Family Simply Nutritious Visionade. We have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101-Food Labeling.

Your label bears claims indicating that Simply Nutritious Visionade is intended to prevent, treat, cure, or mitigate disease. Such claims evidence that the products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the Act (21 U.S.C. 321(g)(1)(B)). The following are examples of such claims found on your label:

> "Bilberry extract....teams up with the antioxidant vitamin C to help protect the eyes against cataracts...." and "We add Taurine and Zinc which helps prevent Macular degeneration."

The labeling found on your "www.knudsenjuices.com" Internet sites also contains claims indicating that the product is intended to prevent, treat, cure or mitigate disease, further evidencing that the products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the Act. The following are examples of such claims found on your websites:

> "Lutein....is added to protect against retinal degeneration," "Bilberry extract.... teams up with the antioxidant vitamin C to help protect the eyes against cataracts....," "We add Taurine and Zinc, which help prevent macular degeneration," "....lutein, a carotenoid that hinders the onset of macular degeneration, the leading cause of blindness in the United States," and "'Macular degeneration will soon take on aspects of an epidemic.' With an estimated 80 million adults 65 years and older in the year 2050, Visionade is a step in the right direction for keeping these individuals seeing 20/20 well into the next millennium."

The claims made for this product, as a legal matter, subject it to the requirements for new drugs [§201(p) of the Act (21 U.S.C. 321(p))] because there is no evidence that this product is generally recognized as safe (GRAS) and effective for its intended uses. Therefore, it may not be legally marketed in the United States without an approved New Drug Application [§505 of the Act (21 U.S.C. 355)]. The product is also misbranded because the label fails to bear adequate directions for use [§502(f)(1) of the Act (21 U.S.C. 352(f)(1))] and is false or misleading [§502(a) of the Act (21 U.S.C. 352(a))], as it suggests that the product is safe and effective for its intended uses when this has not been established.

The product is also misbranded within the meaning of section 403(r)(1)(A) of the Act (21 U.S.C. 343(r)(1)(A)) because the label bears unauthorized nutrient content claims, such as "Lutein....is added...." and "We add Taurine ...." FDA has defined the nutrient content claim "added" by regulation (*see* 21 CFR 101.54(e)(2)). "Added" is authorized to characterize the level of protein, vitamins, minerals, dietary fiber, or potassium in a food that contains at least 10 percent more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) of one of these nutrients than a reference food, which may be similar food or the unfortified version of the food for which the claim is being made. Because lutein and taurine are not among the nutrients for which an "added" claim may be made, the above claims are not authorized and may not appear on the label of this product.

Under the Act, any substance intentionally added to a conventional food, such as juice products like Simply Nutritious Visionade, must be used in accordance with a food additive regulation unless the substance is the subject of a prior sanction (*see* section 201(s)(4) of the Act (21 U.S.C. 321(s)(4)) or is GRAS among qualified experts for its intended use in foods. A substance added to food that is not the subject of a prior sanction, is not GRAS for its intended use, and is not used in accordance with a food additive regulation causes the food containing the substance to be adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)). Such a food cannot be legally marketed in the United States. We are not aware of a basis for concluding that lutein, bilberry extract, or ginkgo is prior sanctioned or is GRAS for use in juice products.

The above violations are not meant to be an all-inclusive list of deficiencies in your product and its labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your letter should also include your basis for concluding that lutein, bilberry extract, and ginkgo are either the subject of a prior sanction or are GRAS for use in conventional foods. Copies of revised labels should also be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

/S/

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition